

(Rel.77-10/98 Pub.603)

FORM 6-4

6-43

Practitioner's Docket No. 1581/128 **PATENT**  
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Kanakaris, et al.

Application No: 09 / 762,602 Group No: 1617  
Filed: March 21, 2001 Examiner: Hui, S.

For: USE OF MISOPROSTOL OR/AND MISOPROSTOL ACID FOR PREPARING DRUG IN ORDER TO CURE SEXUAL DYSFUNCTION IN WOMEN

Commissioner for Patents  
Washington, D.C. 20231

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT  
BEFORE MAILING DATE OF EITHER A FINAL ACTION  
OR NOTICE OF ALLOWANCE (37 C.F.R. § 1.97(c))**

NOTE: An information disclosure statement shall be considered by the Office if filed . . . before the mailing date of either (1) a final action under § 1.113 or (2) a notice of allowance under § 1.311, whichever occurs first, provided the statement is accompanied by either a statement as specified in paragraph (e) of section 1.97 or the fee set forth in § 1.17(p).

NOTE: "If a final action or notice of allowance is mailed in an application and later withdrawn, the application will be considered as not having had a final action or notice of allowance mailed for purposes of considering an information disclosure statement." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "If information submitted during the period set forth in 37 C.F.R. 1.97(c) with a certification is used in a new ground of rejection on unamended claims, the next Office action will not be made final since in this situation it is clear that applicant has submitted the information to the office promptly after it has become known and the information is being submitted prior to a final determination on patentability by the Office. However, the information submitted with a certification can be used in a new ground of rejection and the next Office action made final, [if] the new ground of rejection was necessitated by amendment of the application by applicant. Where the information is submitted during this period with a fee, the examiner may use the information submitted, e.g., printed publication or evidence of public use, and make the next Office action final whether or not the claims have been amended, provided that no other new ground of rejection which was not necessitated by amendment to the claims is introduced by the examiner. See MPEP 706.07(a). If a new ground of rejection is introduced that is neither necessitated by an amendment to the claims nor based on the information submitted with the fee set forth in 37 C.F.R. § 1.17(p), the Office action shall not be made final." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

**CERTIFICATE OF MAILING/TRANSMISSION (37 C.F.R. § 1.8(a))**

I hereby certify that this correspondence is, on the date shown below, being:

**MAILING**

deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231.

**FACSIMILE**

transmitted by facsimile to the Patent and Trademark Office.

Signature

Harriet M. Strimpel, D. Phil.  
(type or print name of person certifying)

Date: October 23, 2001

(Transmittal of Information Disclosure Statement before Mailing Date of Either a Final Action Or Notice of Allowance [6-4]—page 1 of 3)

**WARNING:** "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. § 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63).

### **TIME OF TRANSMITTAL OF ACCOMPANYING INFORMATION DISCLOSURE STATEMENT**

1. The information disclosure statement transmitted herewith is being filed *after* three months of the filing date of this national application or the date of entry of the national stage as set forth in § 1.491 in an international application or after the mailing date of the first Office action on the merits, whichever event occurred last but *before* the mailing date of either:
  - (1) a final action under § 1.113 or
  - (2) a notice of allowance under § 1.311,whichever occurs first.

### **STATEMENT OR FEE**

2. Accompanying this transmittal is

(check either A or B below)

- A.  a statement as specified in 37 C.F.R. § 1.97(e).

**OR**

- B.  the fee set forth in 37 C.F.R. § 1.17(p) for submission of an information disclosure statement under § 1.97(c). (\$240.00).

### **FEE PAYMENT**

(complete this item, if applicable)

3. Applicant elects the option to pay the fee set forth in 37 C.F.R. § 1.17(p) for submission of an information disclosure statement under § 1.97(c) (\$240.00).

Fee due \$ \_\_\_\_\_

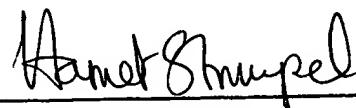
### **METHOD OF PAYMENT OF FEE**

4.

Attached is a check in the amount of \$ \_\_\_\_\_.  
 Charge Account No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_.  
A duplicate of this request is attached.

If any additional fees are due, please charge Account \_\_\_\_\_.

(Transmittal of Information Disclosure Statement before Mailing Date of Either a Final Action Or Notice of Allowance [6-4]—page 2 of 3)



SIGNATURE OF PRACTITIONER

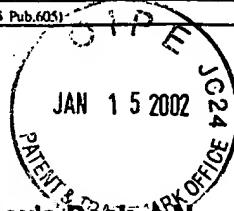
Reg. No. 37,008

Harriet M. Strimpel, D.Phil.  
(type or print name of practitioner)

Tel. No.: (617) 443-9292

Bromberg & Sunstein, LLP  
125 Summer Street, Boston, MA 02110  
P.O. Address

Customer No.: 00-2101



Attorney's Docket No. 1581/125

**PATENT****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: Kanakaris, et al.

Group No. 1617

Serial No.: 09/762,602

Examiner: Hui, S.

Filed: March 21, 2001

For: USE OF MISOPROSTOL OR/AND MISOPROSTOL ACID FOR PREPARING DRUG IN  
ORDER TO CURE SEXUAL DYSFUNCTION IN WOMEN

**Commissioner for Patents**  
Washington, D.C. 20231

**CERTIFICATION FOR INFORMATION DISCLOSURE STATEMENT**  
(37 CFR 1.97(e))

**NOTE:** A certification must state either: "(1) that each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the statement, or (2) that no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the person signing the certificate after making reasonable inquiry, was known to any individual designated in § 1.56(c) more than three months prior to the filing of the statement." 37 CFR 1.97(e).

**NOTE:** "Section 1.97(e) makes it clear that a certification could contain either of two statements. One statement is that each item of information in an information disclosure statement was cited in a search report from a patent office outside the U.S. not more than three months prior to the filing date of the statement. Under this certification, it would not matter whether any individual with a duty actually knew about any of the information cited before receiving the search report. In the alternative, the certification could state that no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual having a duty to disclose more than three months prior to the filing of the statement." Notice of January 9, 1992, 1135 O.G. 13-25, at 13. (emphasis added). Thus: "If an item of information is submitted within three months of being cited in a communication from a foreign patent office in a counterpart foreign application, the certification can be properly made regardless of any individual's previous knowledge of the information." *Id.*, 1135 O.G. at 19.

**NOTE:** "The certification can be based on present, good faith knowledge about when information became known without a search of files being made." Thus, for example, the certification of § 1.97(e) does not preclude the use of the certification in an application by corporations whose practitioners have over the years reviewed thousands of patents and technical publications, even though they are unaware of the relevance of any one thereof to the application. Notice of January 9, 1992, 1135 O.G. 13-15, at 19.

**CERTIFICATE OF MAILING/TRANSMISSION (37 CFR 1.8a)**

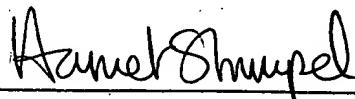
I hereby certify that this correspondence is, on the date shown below, being:

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Date: October 23, 2001

**FACSIMILE**

transmitted by facsimile to the Patent and Trademark Office.

  
Signature

Harriet M. Strimpel, D.Phil.  
(type or print name of person certifying)

**NOTE:** A copy of the foreign search report need not be submitted with the certification. Notice of April 20, 1992 (1138 O.G. 37-41, 40).

**NOTE:** "The phrase 'after making reasonable inquiry' makes it clear that the individual making the certification has a duty to make reasonable inquiry regarding the facts that are being certified. The certification can be made by a registered practitioner who represents a foreign client and who relies on statements made by the foreign client as to the date the information first became known. A registered practitioner who receives information from a client without being informed whether the information was known for more than three months, however, cannot make the certification without making reasonable inquiry. For example, if an inventor gave a publication to the attorney prosecuting an application with the intent that it be cited to the Office, the attorney should inquire as to when that inventor became aware of the publication and should not submit a certification under 37 CFR 1.97(e)(2) to the Office until a satisfactory response is received. The certification can be based on present, good faith knowledge about when information became known without a search of files being made." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

**NOTE:** "Although it is recognized that an individual actually becomes aware of the information in the communication from a foreign patent office sometime after it was mailed, the mailing date of such a communication, if it occurs prior to a first awareness of the same information, would determine the date for filing of an information disclosure statement without a fee" in a certification procedure under § 1.97(e). Notice of January 9, 1992, 1135 O.G. 13-25, at 19 (emphasis added).

**NOTE:** "The certification under § 1.97(e) should be made by a person who has knowledge of the facts being certified. The certification can be made by a practitioner who represents a foreign client and who relies on statements made by the foreign client as to the date the information first became known. A practitioner who receives information from a client without being informed whether the information was known for more than three months, however, cannot make the certification without making reasonable inquiry." Notice of January 9, 1992, 1135 O.G. 13-25 at 19.

**NOTE:** "The term *counterpart foreign patent application* means that a claim for priority has been made in either the U.S. application or a foreign application based on the other, or that the disclosures of the U.S. and foreign patent applications are substantively identical (e.g., an application filed in the European Patent Office claiming the same U.K. priority as claimed in the U.S. application)." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

**NOTE:** "Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent or inventor." 37 CFR 1.56(d) and  
"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:  
(1) each inventor named in the application;  
(2) each attorney or agent who prepares or prosecutes the application; and  
(3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 CFR 1.56(c).

### **IDENTIFICATION OF INFORMATION DISCLOSURE STATEMENT FOR WHICH THIS CERTIFICATION IS BEING MADE**

1. This certification is being made for the Information Disclosure Statement  
 accompanying this certification.  
 filed \_\_\_\_\_  
date \_\_\_\_\_

Certification for Information Disclosure Statement (37 CFR 1.97(e)) [6-8]—page 2 of 4

**CERTIFICATION**

2. I, the person(s) signing below certify

(check appropriate item)

that each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the statement. 37 CFR 1.97(e)(1).

**NOTE:** *The three month period starts from the mailing date of the foreign patent office communication. Notice of January 9, 1992, 1135 O.G. 13-25 at 19. The mailing date is the "date on the communication by the foreign patent office." Notice of April 20, 1992 (1138 O.G. 37-41, 39).*

**OR**

that no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in § 1.56(c) more than three months prior to the filing of the statement. 37 CFR 1.97(e)(2).

**NOTE:** *"The time at which information 'was known to any individual designated in 37 CFR 1.56(c)' is the time when the information was discovered in association with the application even if awareness of the materiality came later." Notice of April 20, 1992 (1138 O.G. 37-41, 40).*

**IDENTIFICATION OF PERSON(S) MAKING THIS CERTIFICATION**

3. The person making this certification is

(check each applicable item)

(a)  the inventor(s) who signs below

**SIGNATURE OF INVENTOR**

(type name of inventor who is signing)

(b)  a person who is substantively involved in the preparation or prosecution of the application, and who is associated with the inventor, with the assignee, or with anyone to whom there is an obligation to assign the application (37 CFR 1.56(c)) and who signs below.

**SIGNATURE OF PERSON**

(type name of person who is signing)

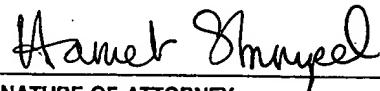
Address of person who is signing

(c)  the attorney who signs below on the basis of the information:

(check each applicable item)

- supplied by the inventor(s).
- supplied by an individual designated in § 1.56(c).
- in the attorney's file.

**NOTE:** "Certification need not be in the form of an oath or a declaration under 37 CFR 1.68. Certification by a registered practitioner or any other individual that the statement was filed within the three-month period of either first citation by a foreign patent office or first discovery of the information will be accepted as dispositive of compliance with this provision in the absence of evidence to the contrary." . . . "A statement on information and belief would not be sufficient." Notice of April 20, 1992 (1138 O.G. 37-41, 39-40).



SIGNATURE OF ATTORNEY

Reg. No.: 37,008

Harriet M. Strimpel, D.Phil.

(type or print name of attorney)

Tel. No. (617) 443-9292

Bromber & Sunstein, LLP

P.O. Address

125 Summer Street

Boston, Ma 02110

Certification for Information Disclosure Statement (37 CFR 1.97(e)) [6-8]—page 4 of 4



Practitioner's Dkt No. 1581/128

**PATENT****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent application

of \_\_\_\_\_ Inventor(s)

for \_\_\_\_\_ Title of invention

**OR**

In re application of: Kanakaris et al.

Application No.: 09/762,602

Group Art Unit: 1617

Filed: March 21, 2001

Examiner: Hui, S.

For: USE OF MISOPROSTOL OR/AND MISOPROSTOL ACID FOR PREPARING DRUG IN  
ORDER TO CURE SEXUAL DYSFUNCTION IN WOMEN**Commissioner for Patents****Washington, D.C. 20231****SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

**CERTIFICATE UNDER 37 C.F.R. § 1.8(a) and 1.10\***  
*(When using Express Mail, the Express Mail label number is mandatory;  
 Express Mail certification is optional.)*

I hereby certify that this correspondence is, on the date shown below, being:

**MAILING**

- deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231

**37 C.F.R. § 1.8(a)****37 C.F.R. § 1.10\***

- with sufficient postage as first class mail.

as "Express Mail Post Office to Addressee"  
 Mailing Label No. \_\_\_\_\_ (**mandatory**)

**TRANSMISSION**

- transmitted by facsimile to the Patent and Trademark Office.

Date: October 23, 2001

Signature

Harriet M. Strimpel, D. Phil.  
 (type or print name of person certifying)

*NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant within any one of the following time periods:*

- (1) *Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);*
- (2) *Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;*
- (3) *Before the mailing date of a first Office action on the merits; or*
- (4) *Before the mailing date of a first Office action after the filing of a request for continued examination under § 1.114."*

*37 C.F.R. § 1.97(b).*

*NOTE: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. § 1.56(a).*

*"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:*

- (1) *each inventor named in the application;*
- (2) *each attorney or agent who prepares or prosecutes the application; and*
- (3) *every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. § 1.56(c).*

*NOTE: The "duty as described in § 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O. G. 13 -25 at 17.*

**WARNING:** "No information disclosure statement maybe filed in a provisional application." 37 C.F.R. § 1.51(d).

### **List of Sections Forming Part of This Information Disclosure Statement**

The following sections are being submitted for this Information Disclosure Statement:

*(check sections forming a part of this statement: discard unused sections and number pages consecutively)*

1.  Preliminary Statements
2.  FORMS PTO/SB/08A and 08B (formerly FORM PTO-1449)
3.  Statement as to Information Not Found in Patents or Publications
4.  Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5.  Cumulative Patents or Publications
6.  Copies of Listed Information Items Accompanying This Statement
7.  Concise Explanation of Non-English Language Listed Information Items
  - 7A.  EPO Search Report
  - 7B.  English Language Version of EPO Search Report
8.  Translation(s) of Non-English Language Documents
9.  Concise Explanation of English Language Listed Information Items (Optional)
10.  Identification of Person(s) Making This Information Disclosure Statement

*(complete the following, if appropriate)*

Sections \_\_\_\_\_, respectively, have been continued on ADDED PAGE(S).

*NOTE: "Once the minimum requirements are met the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).*

**S e c t i o n 1. P r e l i m i n a r y S t a t e m e n t s**

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. § 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

JAN 15 2002

**Section 2. Forms PTO/SB/08A and 08B (formerly Form PTO-1449)****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Karouzakis et al. Attorney Docket: 1581/128  
Serial No: 09/762,602 Art Group Unit: 1617  
Date Filed: March 21, 2001 Examiner Name: Hui, S.  
Invention: Use of Misoprostol Or/and Misoprostol Acid for Preparing Drug in Order to Cure Sexual Dysfunction in Women

**LIST OF PATENTS AND PUBLICATIONS FOR  
APPLICANT'S INFORMATION DISCLOSURE STATEMENT****United States Patents**

Examiner Initials	Reference Number	Document Number	Issue Date	Inventor	Class/Subclass
	AW	6,046,240	04/04/00	See	514/573

Examiner Signature: \_\_\_\_\_

Date Considered: \_\_\_\_\_

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation *if not* in conformance and not considered. Include copy of this form with next communication to applicant.

01581/00128 178348.1

**S ection 6. C opies of L isted I nformation I tems Accompanying This Statement**

*NOTE: 37 C.F.R. § 198(a)(2) requires that any information disclosure statement filed under § 1.97 shall include:*

*"A legible copy of:.*

- (i) Each U.S. patent application publication and U.S. and foreign patent;*
- (ii) Each publication or that portion which caused it to be listed,*
- (iii) For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion. . .*

Legible copies of all items listed in Forms PTO/SB/08A and 08B (formerly Form PTO-1449) accompany this information statement.

*(complete the following, if applicable)*

Exception(s) to above:

- Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.
- Cumulative patents or publications identified in Section 5.

**Section 10. Identification of Person(s) Making This Information Disclosure Statement**

The person making this statement is

(check each applicable item)

(a)  the inventor(s) who signs below

---

**SIGNATURE OF INVENTOR**

---

(type or print name of inventor who is signing)

(b)  an individual associated with the filing and prosecution of this application (37 C.F.R. § 1.56(c))

---

**SIGNATURE OF INVENTOR**

---

(type or print name of inventor who is signing)

(c)  the practitioner who signs below on the basis of the information:

(check each applicable item)

supplied by the inventor(s).  
 supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. § 1.56(c))  
 in the practitioner's file.

Reg. No.: 37,008

Harriet M. Strimpel

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**SIGNATURE OF PRACTITIONER**

Tel. No.: 617/443-9292

Harriet M. Strimpel, D. Phil.

---

(type or print name of person certifying)

Customer No.: 00-2101

Bromberg & Sunstein LLP  
125 Summer Street, Boston, MA 02110